

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

UNITED STATES OF AMERICA and)
STATE OF INDIANA, *ex rel.* [UNDER) Case No.: [UNDER SEAL]
SEAL],)
Plaintiff/Relator,) **FILED UNDER SEAL PURSUANT TO**
vs.) **31 U.S.C. § 3730(b)(2) AND LOCAL**
[UNDER SEAL],) **RULE 5-11**
Defendants.) **DO NOT SERVE OR POST ON PACER**

AMENDED FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

FILED UNDER SEAL

PURSUANT TO 31 U.S.C. §§ 3729 *et. seq.*

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

UNITED STATES OF AMERICA and)
STATE OF INDIANA, *ex rel.* Dr. Rajiv)
Sharma,)
Plaintiff/Relator,) Case No.: 1:20-cv-01984-TWP-DLP
)
vs.)
ADAPTIVE HEALTHCARE SOLUTIONS,)
LLC, THE COBLE GROUP, LLC, DIANA)
KELLEY, DERIN SCOTT, CHELSEA)
MAUER, MARNIE RAE HALL and)
HAROLD COBLE,)
Defendants.)

FILED UNDER SEAL PURSUANT TO
31 U.S.C. § 3730(b)(2) AND
LOCAL RULE 5-11
DO NOT SERVE OR POST ON PACER

AMENDED FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff/Relator Dr. Rajiv Sharma (“Dr. Sharma” or “Relator”), by and through the undersigned attorneys, on behalf of the United States of America and the State of Indiana, complains of the above-named Defendants and each of them as follows:

STATEMENT OF THE CASE

1. Relator seeks to recover, on behalf of the United States of America and the State of Indiana, treble damages and civil penalties arising from false claims, and the creation of false records and statements made or caused to be made and submitted directly or indirectly by the Defendants, to the United States Government and/or the State of Indiana, all in violation of the federal False Claims Act, 42 U.S.C. § 3729, *et seq.*, the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the Indiana False Claims Act, Indiana Code § 5–11–5.5 *et seq.*

2. Relator is a board-certified physician with training in both internal medicine and gastroenterology. He practices primarily in Terre Haute, Indiana where he focuses his practice on GERD, NERD, Inflammatory Bowel Disease (Crohn's & Ulcerative Colitis), Acute and Chronic Pancreatitis, Gastrointestinal Malignancies and Familial Cancer Syndromes. Throughout his career, Dr. Sharma has noticed the impact that allergies and gut health have on the patients that he treats. Through his medical practice and his interest in allergies and gut health, Dr. Sharma learned of Defendants' illegal schemes.¹

3. Upon information and belief, Defendants market, own and/or operate an allergy program, the Adaptive Allergy Program, (the "Allergy Program") placed in practices and businesses (collectively the "Healthcare Providers") around the country, including but not limited to, primary care providers, dermatologists, internal medicine providers, pulmonologists, OB/GYNS, ENT providers, pediatricians, hospitals, and health care systems. Defendants told Dr. Sharma that they had at least twenty (20) locations in which they provided services through the Allergy Program.

4. Defendants contract with the Healthcare Providers to provide allergy testing and treatment services to the Healthcare Providers' patients. These services are provided by employees and agents of Defendants within a designated space at the Healthcare Providers' offices or clinics. Many of the Healthcare Providers' patients, like Dr. Sharma's patients, likely receive health care coverage through the state's Medicaid programs (paid with both state and federal funds), the

¹ Specifically, Dr. Sharma first learned of the Allergy Program when he was looking to expand his practice to Vincennes, Indiana in November of 2018. He met with a doctor who owned Clear View Eye Center. That doctor was going to retire and offered to rent or sell his building to Dr. Sharma. That same doctor mentioned an allergy program he had been operating in conjunction with his eye practice; the doctor claimed to have made over \$400,000.00 off of the allergy practice. After some online research, Dr. Sharma was contacted by Derin Scott who identified himself as the CEO of Adaptive Allergy.

federal Medicaid programs, and other federal or state funded healthcare programs (sometimes referred to herein as “Government Healthcare Programs”).

5. Defendants are engaged in at least three (3) illegal schemes. First, Defendants provide Healthcare Providers with illegal kickbacks in violation of the federal Anti-Kickback Statute, inducing Healthcare Providers to contract with the Defendants to set up Allergy Programs in the Healthcare Providers’ offices or clinics, inducing the Healthcare Providers to refer their patients to the Allergy Programs for testing, related services, and treatments.² These kickbacks take the form of fee-splitting arrangements based on volume and other illegal inducements. Second, Defendants provide or cause to be provided unnecessary medical treatments through the provision of allergen immunotherapy and improperly bill Government Healthcare Providers or cause Government Healthcare Providers to be improperly billed for the “treatments” that they provide. Third, Defendants improperly bill the Government Healthcare Providers or cause Government Healthcare Providers to be improperly billed for “services.” The improperly billed “services” include, but are not limited to, mixing and the dilutions of allergens and sublingual immunotherapy—an unapproved allergy treatment method that involves placing liquid drops of allergens underneath a patient’s tongue.

6. Defendants’ specific wrongful acts include, in addition to other acts described herein, billing or causing the billing to Government Healthcare Programs for: kickback-tainted healthcare resulting from illegally inducing Healthcare Providers to contract with them to provide unnecessary medical services, such as skin testing a large number of patients for considerable amount of allergens, without any consideration of the patients’ individual medical histories;

² Oftentimes, Defendants’ agents and employees who worked at the Allergy Programs would take patients back for testing, “services,” and “treatment,” without the consent, recommendation, or knowledge of the healthcare provider like Dr. Sharma or his nurse practitioners on staff.

providing immunotherapy to patients without any consideration or determination of medical necessity; requiring an unusually high number of injections, to allow for an unusually high number of doses to be billed; and providing unapproved sublingual immunotherapy.

7. All of these schemes clearly violate the federal False Claims Act, the state's False Claims Acts, and the Anti-Kickback Statute by causing the submission of false claims to and other unlawful acts against Government Healthcare Programs through Defendants' false claims, false statements, false reports, false certifications, and other wrongful acts, as described in greater detail below.

8. As a direct result of Defendants' improper practices in violation of the federal False Claims Act, the Anti-Kickback Statute, and the state False Claims Acts, the U.S. and State treasuries have been damaged in a substantial amount yet to be determined.

9. The Relator, Dr. Rajiv Sharma, seeks treble damages, civil penalties, and other relief arising from false claims, and the creation of false records and statements made or caused to be made and submitted directly or indirectly by the Defendants, to the United States Government, all in violation of the federal False Claims Act, the state False Claims Acts, and the Anti-Kickback Statute.

JURISDICTION AND VENUE

10. The Court has jurisdiction over the subject matter of the False Claims Act pursuant to 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court for actions brought pursuant to §§ 3729 and 3730 of Title 31; pursuant to 28 U.S.C. § 1331, which confers federal subject matter jurisdiction for federal questions; and pursuant to 28 U.S.C. § 1345, which confers federal subject matter jurisdiction over actions where the United States is plaintiff.

11. Contemporaneous with the filing of the original Complaint, Dr. Sharma provided the Attorney General of the United States a statement of material evidence and information regarding the allegations herein of which Dr. Sharma is aware, together with a copy of the original Complaint, in accordance with the provisions of 31 U.S.C. § 3730(b)(2).³

12. This Court has personal jurisdiction over each Defendant herein pursuant to 31 U.S.C. § 3732(a) because each submitted, or caused to be submitted, false claims directly or indirectly to the government; and because each has made, used, or submitted, or caused to be made, used, or submitted false or fraudulent records in this District to get false claims paid or approved.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §§ 1391(b) and 1391(c) because each Defendant transacts business that is the subject matter of this lawsuit in the Southern District of Indiana and/or one or more of the acts at issue occurred in this District.

14. This suit is not based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, and to the extent that some allegations or transactions alleged herein have been publicly disclosed, Dr. Sharma is an “original source” of the same within the meaning of the False Claims Act, 31 U.S.C. § 3730(e)(4)(A), and voluntarily disclosed such information to the government. Dr. Sharma gained direct and independent knowledge of the frauds alleged herein through his observations while at his own practice, Digestive Health Associates, LLC in Terre Haute, Indiana.

PARTIES

³ Dr. Sharma also provided the Indiana Attorney General and Inspector General with copies of the original Complaint in accordance with Indiana Code Section 5-11-5.5-3.

The Plaintiff-Relator

15. This action is brought by Relator Dr. Rajiv Sharma (“Dr. Sharma”) on his own behalf and on behalf of the United States of America and the State of Indiana.

16. Dr. Sharma is a citizen of Indiana. Dr. Sharma is a board-certified gastroenterologist in Indiana and is a specialist in diagnosis and treatment of gastrointestinal tract conditions. Dr. Sharma attended Dayanand Medical College in Punjab, India. He completed his Internal Medicine training at Loma Linda University in Loma Linda, California, and he received his Gastroenterology Fellowship training from University of Rochester, in Rochester, New York. During his Fellowship, Dr. Sharma was trained by Dr. Richard Farmer, who is recognized worldwide for his work related to Inflammatory Bowel Disease.

17. Throughout the years, Dr. Sharma has taken an interest in learning more about the underlying causes of his patients’ gastroenterology issues. Over time, this has prompted Dr. Sharma to delve deeper into the role that allergies and gut health play with the gastroenterology symptoms that he sees in his patients.

18. In the course of trying to assist his patients with allergy-related health issues, Dr. Sharma discovered evidence of the illegal schemes discussed herein, and particularly evidence of Defendants’ behavior designed to provide unnecessary medical services to patients, in some cases without medical recommendations or oversight,⁴ and to cause the filing of false claims to Government Healthcare Programs for these services.

19. Dr. Sharma observed the Defendants from November of 2018 through January of 2019, during which time they were providing allergy related services to his patients at his practice in Terre Haute, Indiana. Dr. Sharma discovered evidence of the illegal scheme designed to provide

⁴ Dr. Sharma believes these actions rise to the level of constituting being the unlawful practice of medicine. See § 25-22.5-8-1.

unnecessary medical services to patients and to cause the filing of false claims to Government Healthcare Programs for these services.

The Defendants

20. Defendant Adaptive Healthcare Solutions, LLC (“AHS”) at all relevant times has been a Delaware limited liability company with its principal place of business in Georgia.

21. AHS provided services at Dr. Sharma’s medical practice located at 4445 South 10th Street, Terre Haute, IN 47802 from November of 2018 through January of 2019.

22. Based upon information provided to Dr. Sharma by Defendants, there are at least twenty (20) other locations in which Defendants are operating allergy services with similar practices and clinics.

23. Defendant Harold Coble (“Defendant Coble”) is a resident of the state of Georgia. Defendant Coble is the President of AHS and The Coble Group, LLC.

24. Defendant Diana Kelley (“Defendant Kelley”), the Chief Operating Officer, Director of Allergy Clinical Services with AHS, and she claims to be a “grandfathered” RN.⁵ Upon information and belief, Diana Kelley is a resident of Jacksonville, Florida.⁶

25. Defendant Derin Scott⁷ (“Defendant Scott”), is the Chief Operation Officer of Adaptive Allergy. Upon information and belief, Derin Scott is a resident of New Smyrna Beach, Florida.

⁵ At all times relevant to this lawsuit, Defendant Kelley has portrayed herself as having particular background in medical care and that she was “grandfathered” in from needing certain schooling and licensing.

⁶ Sharma also believes that Defendant Kelley owns a similar allergy scheme named Allergy Treatment Systems, Inc. that uses an “internet based platform.”

⁷ Derin Scott has been named in other lawsuits and has had judgments entered against him for cases involving claims of fraud and deceptive practices. Specifically, Defendant Scott was a defendant *State ex rel. Cooper v. Orion Processing, LLC*, No. 13 CVS 7161, 2017 WL 939317 (N.C. Super. Mar. 7, 2017) along with several other parties, including, his wife Shannon Scott.

26. Defendant Marnie Rae Hall (“Defendant Hall”) was an employee of Adaptive Allergy who performed services in Defendant’s allergy clinic located in Dr. Sharma’s office. Upon information and belief, Marnie Rae Hall is a resident of Terre Haute, Indiana.

27. Defendant Chelsea Mauer (“Defendant Mauer”) was an employee of Adaptive Allergy who performed services in Defendant’s allergy clinic located in Dr. Sharma’s office. Upon information and belief, Chelsea Mauer is a resident of Edwardsport, Indiana.

28. The Coble Group, LLC (“Defendant Coble Group” or “Coble Group”) is a domestic limited liability company with its principal place of business in the State of Georgia. Upon information and belief, the Coble Group also does business under the name Accelerating Billing Company.

LEGAL AND REGULATORY BACKGROUND

The False Claims Act

29. Congress enacted the False Claims Act (“FCA”) which provides, in pertinent part, that: “any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false statement record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729.

30. False certifications constitute false claims under the FCA, as do billing for services that are not “reasonable and necessary for the diagnosis and treatment of illness or injury” or for non-reimbursable services.⁸

The Indiana False Claims and Whistleblower Protection Act

31. In 2005, the State of Indiana passed the Indiana False Claims and Whistleblower Protection Act.

⁸ Indiana has a similar piece of legislation. See Indiana Code § 5–11–5.5 *et seq.*

32. The Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5-1 to 5-11-5.5-18, provides liability for any person who knowingly or intentionally presents false or fraudulent claims for payment to the state, misappropriate state property, or deceptively conceal or avoid payment obligations to the state.

33. Similar to the federal FCA, the state false claims act offers financial awards for whistleblowers for bringing an action on behalf of the state.

The Indiana Medicaid False Claims and Whistleblower Protection Act

34. Indiana also has the Indiana Medicaid False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.7-1 *et. seq.*

35. Under the Indiana Medicaid False Claims and Whistleblower Protection Act, a person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment approval or knowingly makes, uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim liable to the state for a civil penalty.

The Medicare Program

36. In 1965, Congress enacted Title XVII of the Social Security Act, known as the Health Insurance for the Aged and Disabled Program or the Medicare Program (“Medicare”), to pay for the costs of certain healthcare services. An individual’s entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See 42 U.S.C. §§ 426, 426(A).* The United States Department of Health and Human Services (“HHS”) is responsible for the administration and supervision of Medicare, which is funded by taxpayer revenue. The Centers for Medicare and Medicaid Services (“CMS”) is an agency of HHS and is directly responsible for the administration of the Medicare Program.

37. For a medical service to be covered by the Medicare Program, the service must be medically necessary and supported by documentation. *See Title XVII of the Social Security Act § 1862(a)(1)(A) and § 1833(c).*

38. Furthermore, under Titled XI of the Social Security Act, medical services that are provided to Medicare recipients must meet professionally recognized standards of health care—these standards are oftentimes referred to as “national coverage determinations” (“NCD”) and are typically promulgated by CMS.

39. For example, Medicare considers antigens that are administered sublingually to be considered experimental and investigational, and therefore not medically necessary. As such, Medicare will not cover these types of treatments.

40. Antigens will only be eligible for coverage under Medicare if they are administered by injection.

41. As for the use of antigens for immunotherapy, Medicare may approve payment for a reasonable supply of antigens if “1) the antigens were prepared by a physician who is a doctor of medicine or osteopathy, and 2) the physician who prepared the antigens has examined the patient and determined a plan for treatment and a dosage regimen.” *See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §50.4.4.1.*

42. “Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor.” *See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” § 50.4.4.1.*

43. However, Medicare does not cover claims for physician services where there is an Anti-Kickback Statute violation involved in the underlying transaction. Claims submitted to

federal healthcare programs where a kickback was offered, paid, solicited, or accepted are false under the FCA. Providers that seek to bill Medicare must sign a Provider Agreement that states:

I agree to abide by the Medicare laws, regulations, and program instructions that apply to [me] . . . I understand that payment of a claim by Medicare is conditioned upon the claims and the underlying transaction complying with such laws, regulations, and program instructions including, but not limited to Federal anti-kickback statute . . . and on the provider's compliance with all applicable conditions of participation in Medicare.

44. The Defendants have submitted or caused to be submitted false claims to Medicare in violation of the FCA through their illegal schemes including but not limited to 1) the kickback scheme; 2) the provision of unnecessary medical services and treatments; 3) the improperly billing for the mixing and dilution of allergens; 4) the improper mixing of allergens without physician oversight; 5) improper treatment plans—and in some cases providing excessive injections—without physician referrals or oversight; and 6) the improper billing of sublingual immunotherapy.

Medicaid

45. The Medicaid program is a health insurance program for qualified beneficiaries funded by federal and state taxpayer revenue enacted pursuant to Title XIX of the Social Security Act. 42 U.S.C. §§ 1396-1396v. Each state is permitted to design its own medical assistance plan to address the needs of its citizens. *See* 42 U.S.C. § 1396a.

46. For example, the Indiana Family and Social Services Administration (“FSSA”) Office of Medicaid Policy and Planning (“OMPP”) (collectively “FSSA”) oversees the Indiana Medicaid programs. FSSA periodically issues an Indiana Health Coverage Program (“IHCP”) Rendering Provider Agreement (the “Provider Agreement”). The Indiana Health Coverage Program offers providers with the resources and tools needed to conduct business with Indiana Medicaid. The Provider Agreement requires that, as a condition to participate as a provider with

the Indiana Medicaid Program, a provider must agree to comply with all the terms and conditions of the Provider Agreement, including but not limited to:

Section 14. To certify that any and all information contained on any IHCP billings submitted on the Provider's behalf by electronic, telephonic, mechanical, or standard paper means of submission shall be true, accurate, and complete. The Provider accepts total responsibility for the accuracy of all information obtained on such billings, regardless of the method of compilation, assimilation, or transmission of the information (whether by the Provider, the Provider's employees, agents, or a third party acting on the Provider's behalf, such as a service bureau). The Provider fully recognizes that any billing intermediary or service bureau that submits billings to the FSSA or its fiscal agent contractor is acting as the Provider's representative and not that of the FSSA or its fiscal agent contractor. The Provider further acknowledges that any third party that submits billings on the Provider's behalf shall be deemed to be the Provider's agent for the purposes of submission of the IHCP claims. The Provider understands that the submission of false claims, statements, and document.

Section 35. The Provider and its agents shall abide by all ethical requirements that apply to persons who have a business relationship with the State, as set forth in IC § 4-2-6 et seq., IC § 4-2-7, et seq., the regulations promulgated thereunder, and Executive Order 04-08, dated April 27, 2004. If the Provider is not familiar with these ethical requirements, the Provider should refer any questions to the Indiana State Ethics Commission, or visit the Indiana State Ethics Commission Web site at <http://www.in.gov/ethics/>. If the Provider or its agents violate any applicable ethical standards, the State may, in its sole discretion, terminate this Agreement immediately upon notice to the Provider. In addition, the Provider may be subject to penalties under IC § 4-2-6, IC 4-2-7, IC 35-44-1-3, and under any other applicable laws.

(Indiana Health Coverage Program Rendering Provider Agreement).

47. The Indiana Medicaid Program defines allergen immunotherapy as the parenteral administration of allergenic extracts as antigens at periodic intervals, usually on an increasing dosage scale to a dosage maintained as maintenance therapy.

Other Government Healthcare Programs

48. The Federal Employees Health Benefits Program (“FEHBP”) provides healthcare benefits for qualified federal employees and their dependents. FEHBP pays for various health related services, including but not limited to the services at issue in this lawsuit.

49. Other Government Healthcare Programs include federal prison hospitals, Indian Health Services, Federal Employees’ Compensation Act, Workers’ Compensation Programs, Railroad Retirement Board, and Veterans Administration.

50. Reimbursement practices under all federally-funded Government Healthcare Programs closely aligned with the rules and regulations governing reimbursement from Government Healthcare Programs. Defendants knew or recklessly disregarded the fact that their kickback scheme, the provision of the unnecessary medical services, and the improper billing for the mixing of allergens and sublingual immunotherapy violate the FCA.

The Anti-Kickback Statute

51. The Anti-Kickback Statute (“AKS”) prohibits the known and willful offering, paying, solicitation, or receipt of renumeration in case or in kind to induce or reward patient referrals or the generation of business involving any item or service payable by federal healthcare programs, including Medicaid, Medicare, and other Government Healthcare Programs. 42 U.S.C. § 1320a-7b. The AKS prohibits both the offer and the payment of kickbacks, and the solicitation or receipt of kickbacks.

52. Compliance with the AKS is a condition of payment by government health programs, like Medicare and Medicaid.

53. In pertinent part, the AKS provides:

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b.

54. The intent of the AKS is to ensure that patient care will not be improperly influenced by inappropriate compensation from the healthcare industry. All of the government healthcare programs, including but not limited to Medicare and Medicaid, require every provider

who seeks payment from the program to promise and ensure compliance with the provisions of the AKS and other federal laws governing the provision of healthcare services in the United States.

55. As such, any claim that includes services resulting from a violation of the AKS, like the services by the physicians to whom Defendants offered or paid kickbacks and the services provided by the Defendants that resulted from kickbacks are false claims and other unlawful claims under the FCA and the state false claims act.

56. Payment of renumeration of any kind violates the AKS if one or any purpose for that renumeration was to induce referrals. *United States v. Hancock*, 604 F.2d 999, 1001–02 (7th Cir.1979) (reasoning that “[t]he potential for increased costs to the Medicare–Medicaid system and misapplication of federal funds is plain where payments for the exercise of such judgments are added to the legitimate costs of the transaction” and holding that there was a violation of the Anti–Kickback Act Statute where “handling fees” were paid to doctors by laboratory testing company were disguised bribes for referrals).

57. Moreover, giving a person the opportunity to earn money can also constitute an inducement under the AKS.

58. There is a safe harbor exception to the AKS that excludes some conduct so long as the party or parties strictly complied with all the conditions of the safe harbor. However, parties cannot gain protection under the safe harbor by entering into a sham contract that complies with the written agreement requirement and the other safe harbor requirements but does not truly and accurately reflect the actual arrangement between parties.

59. The safe harbor for personal service arrangements requires, among other things, that:

The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in

arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health programs; and

The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 C.F.R. § 1001.952(d) (5) and (7).

60. The financial agreements between the Defendants and physicians, like Dr. Sharma, who are paid renumeration are not protected by the safe harbor where the physicians received a percentage of the collections generated by Defendants.

61. This arrangement is not permissible because the compensation is based in part on the volume or value of services provided, is not set in advance, and the services are provided on an as-needed basis as opposed to being limited to a set schedule.

FACTUAL BACKGROUND

The Allergy Center and Its Testing and Protocol

62. In November of 2018, Dr. Sharma first learned of an allergy practice called Adaptive Healthcare Solutions (“AHS”) that touted its ability to offer immunotherapy to existing practices. Due to the fact that many of Dr. Sharma’s patients suffer from gastrointestinal disorders that could be caused by allergies, Dr. Sharma was interested in learning more about AHS. As such, Dr. Sharma filled out an inquiry on AHS’s website.

63. Shortly thereafter, Dr. Sharma was contacted directly by a man who identified himself as AHS’s CEO, Derin Scott (“Defendant Scott”). Defendant Scott provided Dr. Sharma with information regarding AHS’s business model, its principals, and how AHS partners with

existing practices to improve the practices' revenue without the practices having to incur any out of pocket costs or ongoing expenses.

64. During that conversation, Defendant Scott told Dr. Sharma that AHS was doing business with several practices, including Advent Health and that AHS's President, Hal Coble ("Defendant Coble"), was a former Hospital CEO/CFO who had extensive experience in the healthcare industry. Dr. Sharma was also informed that the Chief Medical Officer of the company was an ENT with a background in allergy treatment.

65. Dr. Sharma subsequently spoke to Defendant Coble.⁹ During that conversation, Defendant Coble discussed various contract terms and how their allergy services (the "Allergy Center") would complement Dr. Sharma's existing medical practice. Dr. Sharma was also informed that AHS had a combined seventy-plus (70+) years of allergy clinic experience.

66. Defendant Coble offered Dr. Sharma a trial period in which his employees would offer allergy testing and treatment at Dr. Sharma's medical practice. Defendant Coble said they would do the trial period to see how it did with "no strings attached." The contract was to include a flat administration fee for the allergy clinic, but with no other out of pocket costs. (*See Allergy Center Services Agreement attached as Exhibit A.*) Defendant Coble further informed Dr. Sharma that he could continue to use his current billing company, HSC, and that AHS would work with HSC to submit all of its bills from the Allergy Center.

67. Based upon the representations made to him by Defendants Coble and Scott about AHS, Dr. Sharma signed an electronic contract with AHS.

⁹ During his own research, Dr. Sharma came across information that Defendant Scott has been involved in legal battles related to a consumer debt relief scam that he was involved with. This concerned Dr. Sharma. When Dr. Sharma asked Defendant Coble about Defendant Scott's past legal troubles, Defendant Coble insisted that it wasn't Defendant Scott's "fault" and that Defendant Scott was a good man.

68. Shortly after signing the first contract, Defendant Coble sent Dr. Sharma a second contract related to medical billing. Specifically, Dr. Sharma was told that AHS needed to use a company called Accelerating Billing Company (“ABC”) to handle all of the allergy related testing and treatment. Unbeknownst to Dr. Sharma, ABC is owned by Defendant Coble.

69. Upon information and belief, the Defendants used ABC to carry out their medical billing fraud, without Dr. Sharma’s knowledge or approval.

70. In November of 2018, AHS began operating the Allergy Center in Dr. Sharma’s office at his Terre Haute location. AHS’s COO, Diana Kelley¹⁰ (“Defendant Kelley”) and Defendant Scott came to Dr. Sharma’s practice to train the two (2) AHS medical assistants who were tasked with running the day to day needs of the Allergy Center. Both of the Allergy Center employees were hired by AHS and on its payroll.

71. Early on, Dr. Sharma began to observe issues with AHS’ employees, their lack of professionalism, their lack of medical knowledge, and the fact that they had a propensity to over test and overtreat where it was not medically warranted—and without Dr. Sharma’s recommendation or knowledge.¹¹

72. Specifically, they were not waiting for a referral by Dr. Sharma or Dr. Sharma’s nurse practitioners before taking patients back to the Allergy Center for testing. This is contrary to what had been decided by Dr. Sharma and Defendant Kelley. Defendant Kelley had created a questionnaire for patients to complete. Dr. Sharma and his nurse practitioners were supposed to

¹⁰ Defendant Kelley, and the other AHS employees, portrayed themselves in a manner that portrayed to others that they had various levels of medical training or backgrounds. Based on his own observations, Dr. Sharma believes this information was inaccurate. Dr. Sharma believes multiple individuals affiliated with AHS were illegally practicing medicine and/or nursing without the requisite training or licenses.

Defendant Kelley also claimed that she had been running allergy clinics for over fifteen (15) years.

¹¹ This became very concerning to Dr. Sharma—the Allergy Center was performing services, testing, and treatment under his license number but he had very limited knowledge or control over what the Allergy Center was doing.

review the questionnaires to determine if allergy testing was necessary; however, in reality, the AHS employees were taking patients for testing without ever talking to Dr. Sharma or his staff.

73. Patients started to complain to Dr. Sharma and his staff about the Allergy Center and its employees. Specifically, patients felt they were being pressured into allergy testing and treatments by the Allergy Center, and were contacted by the Allergy Center despite never having been referred there by Dr. Sharma.

74. For example, Dr. Sharma became aware that the Allergy Center was contacting several of his elderly patients in an effort to convince them that they needed thorough allergy testing and therapy when there was no medical basis for such recommendations.¹²

75. Dr. Sharma contacted Defendant Kelley and reiterated that patients needed to be referred to the Allergy Center. He also asked that the Allergy Center get the patients' permission in writing before the patients were referred to the Allergy Center for testing.

76. The Allergy Center started billing patients' insurance for a year of immunotherapy any time they tested positive for one (1) of the many allergens covered by the skin and blood tests. The Allergy Center was also treating patients for allergies despite having received negative test results.¹³ (See Patient Letter from Jan Deichmiller attached as **Exhibit B**).

77. These aggressive practices by AHS concerned Dr. Sharma so he began his own investigation into the complaints that he was receiving.¹⁴

¹² Dr. Sharma later learned that if the skin test came back negative, the Allergy Center would go ahead and do a blood test to "get better results" without the consent or knowledge of Dr. Sharma and his nurse practitioners.

¹³ At some point, unbeknownst to Dr. Sharma, the Allergy Center started taking the test results from Lab Corps before Dr. Sharma or his nurse practitioners could review them.

¹⁴ Dr. Sharma later learned that the Allergy Center employees were teaching patients and their families how to do their own injections at home without consulting with or informing Dr. Sharma or his nurse practitioners.

78. Dr. Sharma learned that the Allergy Center was testing for a random assortment of allergies like cockroaches and dust mites—not food allergies like Dr. Sharma had requested.¹⁵ Upon learning this information, Dr. Sharma spoke to Defendant Scott in an effort to make the Allergy Center employees change the testing to focus on food allergies.

79. In January of 2019, Dr. Sharma received an invoice from AHS for \$105,000.00. (See Invoice, attached as Exhibit C). The invoice purported to be billing for allergy testing and antigens administered over a four (4) week period. The extreme volume of testing that had occurred and antigens that had been administered over that four (4) week period was very alarming to Dr. Sharma.

80. As such, Dr. Sharma asked to meet with Defendant Coble in January of 2019. He had concerns about the large bill because he had been told the Allergy Clinic would not require any out of pocket costs or ongoing expenses. Dr. Sharma was also concerned because he had heard reports that one of the Allergy Center employees was being extremely aggressive with his patients and insisting that they undergo allergy testing.¹⁶

81. Dr. Sharma met with Defendant Coble on January 18, 2019. During that meeting, Defendant Coble insisted that the program was legitimate and that “legal” had reviewed everything they were doing.

¹⁵ The only reason Dr. Sharma had added the Allergy Center services in conjunction with his own was because he thought his patients gastrointestinal issues may be rooted in undiagnosed food allergies—the random items the Allergy Center was testing for had no bearing on Dr. Sharma’s practice or the needs of his patients.

¹⁶ One of AHS’s employees was also telling patients that they needed to be on a three (3) year treatment plan of weekly injections and that their insurance would be billed for all three (3) years in January of 2019. See Patient Letter – Shirley Downs, attached as Exhibit D.

82. Dr. Sharma asked AHS to see the billing reports, which AHS had been keeping from him. When he finally saw the billing reports, Dr. Sharma realized that AHS had billed over \$400,000 in allergy testing, various treatments, and shots during the first four (4) weeks.¹⁷

83. On January 21, 2019, Dr. Sharma informed the Allergy Center and AHS that he would no longer continue to offer their services and he asked the AHS employees to leave the premises immediately.

84. To date, Dr. Sharma has collected approximately \$135,000 of the \$400,000 that had been billed to the various insurance companies. On the advice of counsel, Dr. Sharma has been putting all of this money in an escrow account until it can be determined how he should proceed.

85. Since terminating his relationship with AHS, Dr. Sharma has learned additional information regarding the manner in which AHS had been operating its Allergy Clinic. Dr. Sharma has learned that AHS employees had been directed to over treat, over test, and push as much allergy treatment as possible. They were also mixing the antigens without any oversight by Dr. Sharma or his nurse practitioners.¹⁸

¹⁷ In some cases, AHS had billed patients' insurance companies for more than one (1) year of treatments, including sublingual drops. SLIT therapy—the administration of immunotherapy serums in the form of drops delivered under the tongue—has not been approved by the Food and Drug Administration. Moreover, many insurance companies, including Government Healthcare Programs like Medicare and Medicaid, do not cover this type of therapy.

For example, The Medicare National Coverage Determination Manual specifically states that antigens are only covered if they are administered by injection.

¹⁸ This practice is illegal. It is also very dangerous for patients. For example, on January 29, 2019, Dr. Sharma learned that the "treatments" the Allergy Center had been administering had caused one of his patients to go to the Emergency Room. The patient had a severe infection in her armpit that ultimately required surgery to remove her sweat gland and growing infection. *See Patient Letter – Denise Dobson*, attached as **Exhibit E**. Another patient reported experiencing debilitating headaches after injecting herself with the "treatments" that had been prepared by the Allergy Center employees. Upon learning this information in February of 2019, Dr. Sharma ordered the patient to stop the treatments immediately. This same patient's insurance was billed for three years of treatments. *See Patient Letter – Shirley Downs*, attached as **Exhibit D**.

86. Defendant Kelly was instructing AHS employees to give six (6) to eight (8) shots per patient despite the patients only needing two (2).¹⁹ (See Text Messages between Defendant Kelley and AHS employee attached as **Exhibit F**).

87. In many cases, AHS was also billing for allergy shots for the subsequent year despite having only serviced the patient on one (1) occasion. (See Text message between AHS billing personnel and Dr. Sharma attached as **Exhibit G**).

88. Shortly after Dr. Sharma closed the Allergy Center and kicked out the AHS employees, Defendant Coble started calling Dr. Sharma multiple times a day and leaving voicemails in an effort to “work things out.”

89. When Dr. Sharma failed to respond to Defendant Coble’s calls and voicemails, Defendant Coble sent a message to Dr. Sharma asking that he pay the invoice and wire the money to a particular account. Defendant Coble copied an individual named Bradley Haskins.²⁰

90. Dr. Sharma refused to pay the invoice or wire the money as requested by Defendant Coble.

¹⁹ It is unclear how or why certain dosage decisions were made. There did not appear to be any consistent protocols or procedures for the treatment process.

²⁰ Bradley Haskins has also been involved with the same World Law litigation and consumer debt scam as Defendant Scott. A district court in the Southern District of Florida entered judgement against Bradley Haskins in 2016; and upon information and belief, Bradley Haskins left the United States and now lives in the Czech Republic. *Consumer Financial Protection Bureau v. Orion Processing, LLC d/b/a World Law Processing, Wld Credit Repair, and World Law Debt; Family Capital Investment & Management, LLC a/k/a FCIAM Property Management, et al.* (S.D. Fla. No. 1:15-cv-23070). The court ordered the defendants in that case to repay nearly \$107 million in consumer redress.

91. On February 6, 1019, Dr. Sharma learned that World Law had filed a complaint against Dr. Sharma with the Indiana Medical Licensing Board.²¹

Billing Immunotherapy

92. Government Healthcare Programs impose restrictions on the provision and billing of immunotherapy.

93. For example, in relevant part, the Medicare Benefit Policy Manual provides that “payment be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.”

94. Immunotherapy can also be properly billed by a physician if the physician writes a prescription for the immunotherapy and has it prepared to his specifications.

95. Additionally, the Medicare Claims Processing Manual states that

if a patient’s doses are adjusted, e.g., because of patient reaction, and the antigen provided is actually more or fewer doses than originally anticipated, the physician is to make no change in the number of doses for which he or she bills. The number of doses anticipated at the time of the antigen preparation is the number of doses to be billed. . . . This means that in cases where the patient actually gets more doses than originally anticipated (because dose amounts were decreased during treatment) and in cases where the patient gets fewer doses (because the amounts were increased), no change is to be made in the billing.

²¹ Dr. Sharma believes World Law is the same “law firm” that Defendant Scott and Bradley Haskins have used to run their consumer debt scam. This “law firm” has already had judgments entered against it.

Around that same time that Dr. Sharma learned of the complaint that World Law filed against him, an anonymous individual posted on the internet that Dr. Sharma was fraud and simply takes patient’s money. Despite asking for the assistance of a friend who used to be involved with law enforcement, Dr. Sharma has been unable to determine who posted this review.

Dr. Sharma believes that one or more of the Defendants have been trying to intimidate him and stop him from his pursuit of exposing their fraudulent scheme.

In other words, the physician can create a 10ccs vial and bill for the full 10ccs even if it turns out the patient only required a very small dosage due or had an adverse reaction and had to stop treatment.

Defendants' Anti-Kickback Statute Violations

96. Defendants have each individually engaged in a scheme to pay kickbacks to physicians in exchange for referrals for allergy testing and treatments.

97. Defendants operate and market their fraudulent scheme by providing “in-office” allergy testing through an Allergy Center at the physicians’ office. The Allergy Center scheme requires the physician to provide a dedicated room with a refrigerator and the Defendants provide the “trained” employees and equipment. The physicians are expected to refer their patients to be tested via skin test or blood test at the Allergy Center. The blood tests are then sent to Lab Corps.

98. The Defendants’ employees interpret the test results and make a “diagnosis” without talking to anyone affiliated with the Healthcare Providers, including the physicians, the nurse practitioners, or physician’s assistants, or even making the test results available for review.²²

99. The Defendants’ employees then develop a treatment plan and make recommendations to the patients without physician supervision.

100. In some cases, the Defendants’ employees told the patients they had received positive test results and started them on courses of treatment despite the tests actually being negative.

101. The Defendants’ employees are also responsible for mixing the antigens, administering injections, and teaching patients how to administer their own injections at home—all without any supervision or involvement by the Healthcare Providers.

²² It is unclear how they are capable or qualified to develop treatment plans and administer treatments.

102. In some cases, Defendants provided sublingual immunotherapy instead of subcutaneous injections.

103. All of these services are billed to insurance. Because sublingual therapy is not covered by most insurance companies, it is possible that Defendants were billing the service as immunotherapy injections.

104. Regardless of how or where the immunotherapy is provided, the physicians assume responsibility for the delivery and administration of medication of unknown type or quality.

105. However, the Defendants and their employees intentionally hid information, test results, and treatment plans from the Healthcare Providers making it difficult if not impossible to have any form of control or oversight over the allergy testing and immunotherapy processes.

106. In exchange for the services provided, the Healthcare Providers and Allergy Center bill Government Healthcare Programs for these services—using Defendant Coble’s billing company The Coble Group, LLC d/b/a Accelerating Billing Company—and then split the fee received from the Government Healthcare Program with the Defendants.

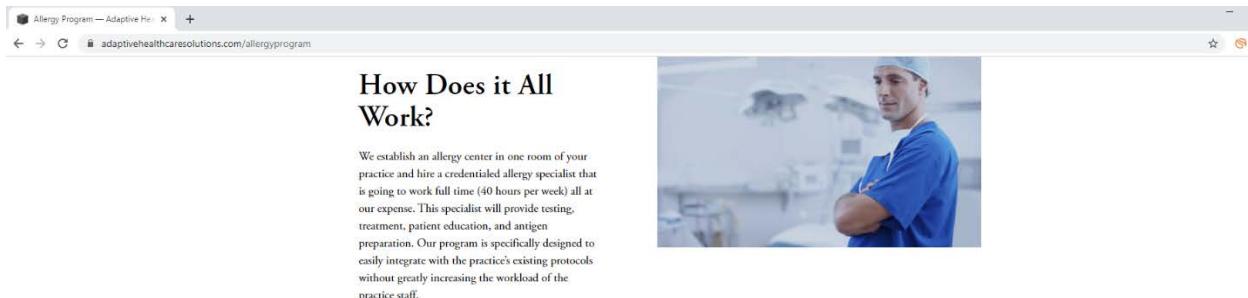
107. This scheme is marketed to Healthcare Providers as “[p]roviding medical practices with a way to retain patients & add an extra stream of revenue to their bottom line with zero out of pocket costs or ongoing expenses.”

108. The website describes the program as follows:

How Does it All Work?

We establish an allergy center in one room of your practice and hire a credentialed allergy specialist that is going to work full time (40 hours per week) all at our expense. This specialist will provide testing, treatment, patient education, and antigen preparation. Our program is specifically designed to easily integrate with the practice’s existing protocols without greatly increasing the workload of the practice staff.

109. The website plainly states, among other things, that it will provide extensive assistance with zero cost and that its program is compliant with all federal and state laws, covered by “ALL” insurance carriers, and the treatment is safe and effective:



How Does it All Work?

We establish an allergy center in one room of your practice and hire a credentialed allergy specialist that is going to work full time (40 hours per week) all at our expense. This specialist will provide testing, treatment, patient education, and antigen preparation. Our program is specifically designed to easily integrate with the practice's existing protocols without greatly increasing the workload of the practice staff.



All the Essentials with Zero Cost.

Our company will provide your practice with all of the following program essentials at no cost to your practice:

THE ANTIGEN	FULL-TIME SPECIALIST	TRAINING MATERIALS
Is a molecule capable of inducing an immune response. Sometimes antigens are part of the host itself in an autoimmune disease.	Designation depends on state requirements but someone who works full time in your allergy center.	Material and information for Doctors and patients.
PROGRAM TRAINING	BILLING / CODING ASSISTANCE	MEDICAL SUPPLIES
Training for full time tech, clinic staff and each patient.	We help direct you with CPT codes and recommendations on Billing.	We supply all medical supplies related to Allergy testing and Treatment.



It's a Win-Win Situation for Patients & Practices.

- Zero Capital & On-going Expenses
- Seamless Integration to your Practice
- Most Everything Provided Including On-site Specialist
- Assistance with Billing, Coding & Documentation
- Allows You to Retain Patients Instead of Refer
- \$1,000-\$2,000 NET Profit per Patient (conservatively)



Requirements:

- 1 Room for Allergy Center
- 1 designated refrigerator
- 40-hour work week
- Insurance Verification & Billing as Payers



The screenshot shows a web browser window with the URL adaptivehealthcaresolutions.com/allergyprogram. The main heading is "WHY DOES YOUR CLINIC NEED AN ADAPTIVE ALLERGY CENTER?". Below the heading is a paragraph of text. To the right is an image of a person in blue scrubs holding a clipboard.

With over 70 years of Allergy experience, our team has seen that over the last decade Environmental Allergies have become more prevalent. Around 60% of individuals have some sort of Environmental Allergies. Unfortunately only 1% are being properly treated. Allergists are booked up and most practitioners are just masking the symptoms for a temporary cover up. Our program is designed so that not only do you get to retain your patients instead of referring them out, but you can greatly improve patient health and root out allergic disease as an underlying condition.

The screenshot shows a web browser window with the URL adaptivehealthcaresolutions.com/allergyprogram. The main heading is "4. THE NUMBER: IS IT REALLY WORTH IT?". Below the heading is a sub-headline: "We'll tell you why your patients need this program and how it benefits them."

We Make it Easy to Grow Your Income

Adding a stream of revenue to your business while giving patients what they need. It's the definition of a win-win scenario.

SIMPLE BILLING PROCESS

We help train your staff to make sure it's all done within the billing guidelines. Your practice bills insurance. Insurance pays you, and then you pay us. It's that simple!

70% CONVERSION RATE

From our internal stats, 70+ out 100 patients tested will elect for therapy.

\$1,000 - \$2,000 / PATIENT

Covered by the insurance carriers, you will conservatively net \$1,000 to \$2,000 profit per patient.



110. The website touts that AHS provides a specialist to run the Allergy Center and who handles all “testing, treatment, patient education, and antigen preparation” all without “greatly increasing the workload of the practice staff.” The Healthcare Providers’ lack of involvement, control, and oversight with respect to the Defendants’ activities in the Allergy Center make it clear that the payments retained by the Healthcare Providers are kickbacks.

111. By providing the medical services of skin testing, blood testing, and immunotherapy preparations, without the required level of physician supervision to meet the applicable standards of care, and then splitting the fees with the Healthcare Providers, the Defendants are engaged in a clear kickback scheme in violation of the AKS and the state and federal FCA.

Unnecessary Medical Services

112. According to the website, Defendants claim to “make it easy to grow your income” and “70+ out of 100 patients tested will elect for therapy.”



We Make it Easy to Grow Your Income

Adding a stream of revenue to your business while giving patients what they need. It's the definition of a win-win scenario.

SIMPLE BILLING PROCESS

We help train your staff to make sure it's all done within the billing guidelines. Your practice bills insurance. Insurance pays you, and then you pay us. It's that simple!

70% CONVERSION RATE

From our internal stats, 70+ out 100 patients tested will elect for therapy.

\$1,000 - \$2,000 / PATIENT

Covered by the insurance carriers, you will conservatively net \$1,000 to \$2,000 profit per patient.

When compared to the national average, as reported by the American Academy of Allergy Asthma & Immunology, the 70+ conversion rate reported by the Defendants is alarmingly high. The extremely high numbers reported by Defendants suggests a gross abuse of a potentially therapeutic treatment—it is also reducing the available supply of treatments for individuals who can truly benefit from it. Even more concerning, the Defendants lied to patients about the results in order to induce them into accepting treatment.

113. For example, one of Dr. Sharma's patients, Jan Deichmiller, who was treated by the Defendants at the Allergy Center after receiving a "positive" result for Candida Albicans. Defendants' employee insisted that she needed to start daily treatment immediately. Ms. Deichmiller was able to obtain her test results from Lab Corps after Dr. Sharma stopped the Allergy Center from offering services in his practice. According to their records, her results for Candida Albicans was 0.11—with 0.10 being negative and 0.10 to 0.31 being equivocal or low.

(See Patient Letter – Jan Deichmiller attached as **Exhibit B**). It is unclear why the Defendants misled the patient with regards to her test results.

114. Other patients experienced extreme reactions whatever they were being “treated” with. In one case the reaction was so severe, that the patient developed a severe infection requiring surgery and the removal of her sweat glands. *See* Patient Letter – Denise Dobson attached as **Exhibit E**.

115. Since ending his relationship with Defendants, Dr. Sharma has received numerous complaints and concerns from patients and employees regarding Defendants’ questionable testing practices, treatment procedures, billing practices, and adverse reactions to the treatments that were provided. Defendants were clearly operating in a manner that put patients’ health and safety at risk in an attempt to increase profits.

116. By indiscriminately testing for and prescribing immunotherapy for patients who do not need it, and violating the standards of care in the testing and prescribing of immunotherapy, Defendants are providing unnecessary and improper medical services. These services place patients at risk of harm and improperly cost Government Healthcare Programs enormous sums of money.

Improper Billings for the Mixing and Dilutions of Allergens

117. Government Healthcare Programs, including Medicare and Medicaid, impose strict restrictions on the billing of allergen immunotherapy.

118. When it is determined that a patient is a candidate for immunotherapy, the physician should prescribe the appropriate serum for the injections and determine the appropriate mixture of antigens.

119. Once the serum is received by the physician, the physician should dilute the serum to the appropriate level before beginning immunotherapy. Generally, the standard of care requires that several levels of dilution occur before the proper maintenance dose is reached.

120. Moreover, according to the relevant guidelines, the antigens should only be mixed and billed for up to twelve (12) months at a time.

121. However, upon information and belief, the Defendants were billing, in some cases, for treatments two (2) or three (3) years in advance. This wrongful practice greatly increases Defendants' potential revenue and the revenue of the physicians that they are working with, and violates the billing requirements of the Government Healthcare Programs, including Medicare and Medicaid.

Improper Billing of Sublingual Drops

122. As previously discussed, sublingual drops are an allergy treatment that involve the placement of liquid allergens underneath the patients' tongues.

123. This treatment is not approved by the Food and Drug Administration, and cannot be billed to any Government Healthcare Program or third party insurance carrier.

124. Despite this explicit probation, Defendants ordered sublingual drops for patients and billed or caused the physicians to bill for this treatment—it is unclear at this time how it was being coded. It is possible that they were being coded as subcutaneous injections.

125. The wrongful billing for sublingual drops to the Government Healthcare Programs by or caused by Defendants violates the FCA and state FCA.

COUNTS AGAINST DEFENDANTS

COUNT I

Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and (B)

126. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 *et seq.*, amended.

127. Based upon the acts described above, Defendants knowingly presented, or caused the physicians to present, to the United States under the Government Healthcare Programs, false claims for payment or approval, and made, used, and caused to be made and used false records and statements material to false claims as a result of their kickback scheme, their provision of unnecessary medical services, their improper billing of the mixing and dilutions of allergens and the improper billing of sublingual drops.

COUNT II
Violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b

128. Each claim for reimbursement for Defendants' services represents a false claim for payment because each allergy test and immunotherapy submitted for payment by a physician for services provided at an Allergy Center carried with it a false certification by the healthcare provider that the service it provided complied with the AKS.

129. Defendants have violated the AKS by implementing programs that provided a direct and substantial financial incentive to induce the physicians to use the Defendants' allergy services and allow them to place Allergy Centers within their practices.

130. Unaware of the falsity of the records, statements, and claims made or caused to be made by the Defendants and in reliance on the truthfulness and accuracy of the Defendants' certifications, the United States paid and continues to pay on the claims that would not be paid but for Defendants' wrongful actions and omissions.

131. As violations of the AKS, the material misrepresentations made by Defendants to induce the use of their services constitute false claims and statements under 31 U.S.C. § 3729 *et seq.* pursuant to 42 U.S.C. § 1320a-7b(g).

COUNT III

Violations of the Indiana False Claims Act, Indiana Code § 5–11–5.5 et seq.

132. The State of Indiana was unaware of the Defendants' wrongful and illegal practices and paid the claims submitted by health care providers and third party payers in connection with the Defendants' wrongful and illegal practices.

133. As a result of the Defendants' violations of Indiana Code § 5–11–5.5 *et seq.*, the State of Indiana has been damaged to the extent of hundreds of thousands of dollars, exclusive of interest.

COUNT IV

**Violations of the Indiana Medicaid False Claims and Whistleblower Protection Act,
Indiana Code § 5-11-5.7-1 et. seq.**

134. The State of Indiana was unaware of the Defendants' wrongful and illegal practices and paid the Medicaid claims submitted by health care providers and third party payers in connection with the Defendants' wrongful and illegal practices.

135. As a result of Defendants' violations of Indiana § 5-11-5.7-1 *et. seq.*, the State of Indiana has been damaged to the extent of hundreds of thousands of dollars, exclusive of interest.

PRAYERS FOR RELIEF

136. Relator prays that this Court:

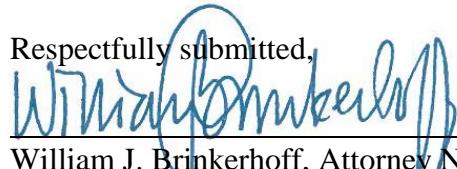
- a. Enter judgment against Defendants for Count I in an amount equal to three (3) times the amount of damages the United States Government has sustained, plus civil penalties for each false claim made in violation of 31 U.S.C. § 3729;
- b. Award the Relator the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act;

- c. Enter judgment against Defendants for Count II, and for all awards and damages required and permitted by the Anti-Kickback Statute;
- d. Enter judgment against Defendants, to the State of Indiana, for all awards and damages required and permitted by the Indiana Medicaid False Claims and Whistleblower Protection Act;
- e. Award Relator a fair and reasonable amount pursuant to Indiana Code § 5–11–5.5 *et seq.*;
- f. Award Relator all reasonable attorneys' fees, costs, and expenses;
- g. Award pre-judgment and post-judgment interest; and
- h. Award the United States and the Relator with all other relief both in law and in equity, to which they are entitled.

JURY DEMAND

Relator, on behalf of himself and the United States Government and the State of Indiana, demands a jury trial on all issues so triable.

Respectfully submitted,


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Alexandra J. Blackwell, Attorney No. 33963-06
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Counsel for Dr. Rajiv Sharma

The foregoing *Amended False Claims Act Complaint and Demand for Jury Trial* was not served on any Defendant pursuant to 31 U.S.C. § 3730(b)(2) or until further notice from the Court.



William J. Brinkerhoff